

# **Exhibit 1**

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June 28, 2017

Via Electronic Mail

Patrick R. Runkle, Esq.  
Consumer Protection Branch  
United States Department of Justice  
450 Fifth Street, NW  
Sixth Floor South  
Washington, D.C. 20001

Re: *United States v. USPlabs, LLC, et al.*, Case No. 3:15-cr-00496-L  
Request for Additional Expert Discovery

Dear Patrick:

We write on behalf of defendants USPlabs, LLC (“USPlabs”), Jacob Geissler, Jonathan Doyle, and Matthew Hebert (“the Defendants”) regarding items for discovery under Fed. R. Crim. P. 16(a)(1)(E)-(G). It has come to our attention that the Government’s recent “production of materials associated with the expert witness disclosure,” per your May 1, 2017 letter, did not contain certain relevant materials related to anticipated expert witness testimony identified by the Government’s Notice of Testimony Under Federal Rules of Evidence 702, 703, and 705 (“Government’s Notice”). Dkt No. 222. These involve information material to preparing the Defendants’ defense and relating to the bases of the expert witnesses’ opinions, and therefore must be produced. Specifically, Defendants request production of the following material, which appears to be missing from the Government’s document production to date.

- I. Regarding all of the Government’s proposed experts:
  - A. Documentation of all payments received by each expert from any arm of the federal government, including CDC, NIH, and FDA
  - B. Engagement letter for each expert

- C. All of each expert's prior expert reports, deposition transcripts, and trial/hearing transcripts
- D. Workpapers relating to each expert's noticed testimony
- E. All communications between each expert and any alleged victim of USPlabs products (or the alleged victim's lawyers)
- F. All communications between or among any of the experts designated by the Government

II. Regarding the noticed expert testimony of **Dr. Herbert Bonkovsky**:

- A. All communications between Dr. Bonkovsky and any other member of the DILIN network (DILIN) regarding (1) USPlabs or any of its products, (2) aegeline, or (3) any other ingredient in OEP-NF
- B. All documents relating to Dr. Bonkovsky's appearance on January 19, 2016 episode of "Frontline," and any other statement to the media
- C. All communications between Dr. Bonkovsky and any employee of the University of Mississippi, including but not limited to Drs. Ikhlas Khan and Mahmoud ElSohly, regarding the testing and analysis of OEP or any of the ingredients therein
- D. All communications with any member of phytochemical Services, Inc (PSI) regarding the testing and analysis of OxyElite Pro ("OEP") or any of the ingredients therein

III. Regarding the noticed expert testimony of **Dr. Mahmoud ElSohly**:

- A. Documents sufficient to evidence the chain of custody for every sample tested by Dr. ElSohly or provided to Drs. Gurley, Koturbash and Boerma for use in their feeding study
- B. All communications between and among Dr. ElSohly and the members of his team (Drs. Ikhlas Khan, Amar Chittiboyina, Bharathi Avula, and Waseem Gull, and Mr. Timothy Murphy)
- C. All communications between Dr. ElSohly and Drs. Daniel Armstrong or Ying Zhang regarding DMAA or any USPlabs product

- D. All communications between Dr. ElSohly and Dr. Yi Jin, Xu Xishuangbanna, Jinghua Yang, Wei-Dong Zhang, Juan Su, Dean Guo, or Min Yang relating to the collection or authentication of geranium samples for use in analyzing whether DMAA occurs naturally in geranium
- IV. Regarding the noticed expert testimony of **Drs. Bill Gurley, Igor Koturbash, and Marjan Boerma:**
- A. All unpublished documents pertaining to the laboratory's experience with the strains of mice identified in the disclosure, including background rates of liver and other effects observed in untreated animals
  - B. All unpublished feeding and gavage studies conducted in this laboratory on other compounds and involving any of the mouse strains used for OEP
  - C. Documents pertaining to the laboratory's compliance with FDA Good Laboratory Practices regulations, or other quality control guidelines
  - D. For each of the extractions of OEP in various solvents that were performed, all documentation of the temperature of the extraction and the rpm of the subsequent centrifugation used to separate the supernatant.
  - E. For each OEP study, all documents showing the source and health status of animals used in the study
  - F. For each OEP study, all documents showing how animals were randomized among dose groups
  - G. For each OEP study, all documents that describe the specific steps used to prepare and verify the gavage solutions used for dosing (all dose groups) and the amounts of solution delivered
  - H. For each OEP study, all documents that describe the specific steps used to prepare and verify the test substance concentrations in the feed at each dose level, and the stability of the test material in the feed over the duration of the study
  - I. For each OEP study, all documents that report the body weights and food intake for each animal over the duration of the study to document the intake of the test substance

- J. For each OEP study, all documents that record all cage-side observations made at and following initiation of dosing throughout the study
  - K. All publications or other information documenting the relevance to humans of the liver findings in the OEP studies
  - L. Relevant literature to justify that the amount of caffeine and yohimbine given to the mice in the 1x, 2x, and 3x groups was not expected to cause toxicity to any organs in the animals
  - M. Reasons why at least 8 of the control/vehicle animals did not have any reported ALT/AST and miR-122 values reported (and were instead listed as N/A), as compared to “1” in the OEP groups
- V. Regarding the noticed expert testimony of **Dr. Nicholas Oberlies**:
- A. Documents reflecting or relating to Dr. Oberlies’ research on 1,3-DMAA’s chirality and the stereoisomers produced both naturally in the geranium plant and synthetically
  - B. All studies consulted by Dr. Oberlies regarding the natural and synthetic production of 1,3-DMAA, aegeline, Yohimbine, and *Cynanchum Auriculatum*
  - C. Documents reflecting Dr. Oberlies’ testing of the 1,3-DMAA, aegeline, Yohimbine, and *Cynanchum Auriculatum* used in USPlabs’ dietary supplements, including lab notebooks and documents sufficient to show the batch and lot numbers of the USPlabs’ supplements Oberlies tested
  - D. Documents reflecting or relating to Dr. Oberlies’ research on aegeline, including its chirality, the stereoisomers produced both naturally and synthetically, the evaluation of “a series of dietary supplements” referenced on page 71 of the Government’s, and the biological activity of aegeline’s enantiomers and its racemic mixture
  - E. Documents reflecting or relating to Dr. Oberlies’ research on Yohimbine, including its chirality, the stereoisomers produced both naturally and synthetically, and the alleged differences between synthetic and naturally-produced Yohimbine
  - F. Documents reflecting or relating to Dr. Oberlies’ research on *Cynanchum Auriculatum*, including studies showing “the differences between

consuming the powdered root of *C. auriculatum* vs an extract thereof vs the pure compound, wilfoside K1N” and “the suite of constituents present in the entire root powder vs the suite of constituents one would observe in an extract of the root powder”

VI. Regarding the noticed expert testimony of **Dr. Karl Klontz**:

- A. All documents relating to Dr. Klontz’s contemplated submission for publication in the New England Journal of Medicine of any articles by Dr. Klontz regarding any USPlabs product (*see, e.g.*, GOV-01549258 and GOV-01552022)
- B. All documents relating to Dr. Klontz’s contemplated submission for publication in the American Journal of Preventive Medicine of any articles by Dr. Klontz for publication regarding any USPlabs product (*see, e.g.*, GOV-01548475)
- C. Any correspondence between Dr. Klontz and any editorial member or reviewers of the American Journal of Preventive Medicine
- D. All documents relating to Dr. Klontz’s contemplated submission for publication in the Journal of the American Medical Association (JAMA) of any articles by Dr. Klontz for publication regarding any USPlabs product (*see, e.g.*, GOV-01549973)
- E. All communications between and among Dr. Klontz and the “skeletal crew” (*see* GOV-01548475) that helped Dr. Klontz review the medical files regarding that review or any USPlabs product
- F. All documents relating to the 45 medical records that Dr. Klontz told the New Zealand government he reviewed, to the extent those records have not already been produced (*see, e.g.*, GOV-01550340)
- G. All communications with Paul Howard at the National Toxicology Program, including but not limited to, discussions involving analysis and results of any OEP and aegeline tests (*see, e.g.*, GOV-01550424)
- H. All communications between and among Dr. Klontz and members of DILIN, including but not limited to Victor Navarro and Robert Fontana
- I. All communications with employees, members, or affiliates of the Centers for Disease Control and Prevention, the Department of Defense, the

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University of North Carolina, or Duke University regarding testing of blood samples from individuals who purportedly experienced hepatitis following OEP use and the identification of control subjects (*see, e.g.*, GOV-01550007 and GOV-01550216).


VII. Regarding the noticed expert testimony of **Ms. Catherine D. Tucker**:

- A. Workpapers underlying Ms. Tucker's creation of the charts attached as Exhibit 16 to the Government's Notice, including without limitation any notes taken by Ms. tucker in connection therewith

The Government is obligated to produce all such documents within its possession, custody or control because they (1) are "material to preparing [Defendants'] defense" (*see* Rule 16(a)(1)(E)(i)), (2) relate to "the results or reports of ... any scientific test or experiment" and otherwise meet the requirements of Rule 16(a)(1)(F), and (3) are potentially exculpatory under *Brady*.

Accordingly, please produce promptly all documents described herein to the extent they have not previously been produced. To the extent that any documents are withheld from production based on privilege, please identify those documents by category and the purported privilege(s) on which the withholding is based. Finally, to the extent that the Government's position that documents in the possession of its experts are not within the Government's "possession, custody or control," please memorialize that position in writing and identify any legal authority supporting that position.

Sincerely,

  
Patrick F. Linehan

*Counsel for USPlabs, LLC*

cc: Michael Uhl, Esp.  
Michael P. Gibson, Esq.  
Richard B. Roper, Esq.  
S. Cass Weiland, Esq.